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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCELWAIN, ELIZABETH F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/27/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/883,797	JAWORSKI ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13,16,17 and 31-40* is/are pending in the application.

4a) Of the above claim(s) *11-13,16,17,31,32,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-37 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group VIII, claims 33-37 and 40 and to SEQ ID NO: 2, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that Groups I-VII should form a single group and Groups VIII-XIV should be combined into a single group. Applicants state that the nucleotide sequences represent related sequences with similarity ranges from 42.3-70.5% and encoding amino acid sequences of 42.0-75.8%, so it would not be an undue burden to search these sequences, since a search for one would encompass a search for the others, and is supported by the Examiner's classification of the sequences together in the same class. Furthermore, applicants point out that the nucleic acid sequences were examined together in a single group in the parent application.

This is not found persuasive because Groups I-XIV are properly restricted, as stated in the last office action. The sequences are properly restricted one from each of the others, given that they are divergent sequences having as little as 42% sequence similarity. Therefore, a separate search would be required for each sequence, and this would create an undue burden for search and examination. In addition, distinct inventions may be classified in the same class. And while the sequences were examined together in the parent application, the present claims are not to specific sequences, but to any sequence that encodes a polypeptide having at least 80% identity to each of the recited sequences. Therefore, each of the recited sequences represents a whole genus of sequences and would require a different search. Additionally, since the time the parent case was examined, the sequence databases have increased in size exponentially and it takes much longer to search each sequence. So, while it was not

determined to be a burden to search all of the sequences in the parent case, it does represent a serious burden at the present time and in view of the breadth of the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-13, 16, 17, 31, 32, 38 and 39 are withdrawn from consideration as drawn to nonelected inventions.

The PTO-1449 forms filed June 18, 2001 and August 26, 2002 have been signed. The sequence Accession numbers have been considered, but will not be printed if the case issues as a patent, because no dates have been provided.

Claims 33 and 40 are objected to for reciting non-elected inventions in the form of the non-elected sequences.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 and claims 34-37 dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is indefinite in the recitation of "a transgenic plant containing a nucleic acid", since it is unclear if the plant has been transformed with the nucleic acid identified in the

claims. In addition, the recitation of "containing" makes it unclear whether the nucleic acid has integrated into the genome of the plant.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-37 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-20, 44, 51 and 58 of U.S. Patent No. 6,307,128. Although the conflicting claims are not identical, they are not patentably distinct from each other because a plant transformed with a nucleic acid sequence

that encodes a polypeptide with at least 80% identity to SEQ ID NO: 2 and a method of transforming a plant with said nucleic acid sequence would have been obvious over a plant transformed with a nucleic acid encoding SEQ ID NO: 2 and method of the same.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-37 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a transgenic plant containing a nucleic acid sequence that encodes a polypeptide having at least 80% sequence identity to SEQ ID NO: 2. However, it is unclear what the functional activity of such sequences would be. Therefore, a plant comprising said sequence has not been adequately described, given the uncertainty regarding the functional activity of any sequence having at least 80% sequence identity to SEQ ID NO: 2. In addition, with regards to claims 37 and 40, the specification does not adequately describe which sequences that have at least 80% sequence identity to SEQ ID NO: 2 would confer altered levels of very long chain fatty acids to a plant. It is unclear from the description provided in the specification which structural features of the polypeptide are required to confer the claimed activity.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-37 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 33-37 and 40 are drawn to a transgenic plant containing a nucleic acid sequence that encodes a polypeptide having at least 80% sequence identity to SEQ ID NO: 2 and a

method of altering the levels of very long chain fatty acids in a plant by transforming a plant with said nucleic acid.

While the specification discloses that nucleic acid sequences encoding a protein having fatty acid elongase activity, there is no evidence provided that other sequences that encode polypeptides having at least 80% identity to SEQ ID NO: 2 will have the same effect or any other effect when transformed into a plant. Yet, the alteration of plant phenotype by tranforming a plant with a heterologous gene construct is highly unpredictable, as evidenced by De Luca. De Luca teaches the unpredictability of modifying metabolic pathways in a plant (see the paragraph bridging the columns of page 225N and the last paragraph of page 228N).

In addition, identification of related sequences that will encode enzymes having a specific activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the functionality or more knowledge of the particular structural features that are required for conferring this function. Therefore, it would require undue experimentation to establish how to use the claimed sequence, given the uncertainty of

predicting the activity of an enzyme from an amino acid sequence, as stated above. In addition, the specification fails to provide guidance with regard to how to evaluate transformed plants for any other activities.

Given the lack of guidance in the specification for producing and identifying plants with altered plant phenotype, the absence of working examples of plants transformed with other sequences within the scope of the claims; the unpredictability of the effect of polypeptides encoded by other sequences on a plant; the unpredictability with regard to modifying metabolic pathways by transforming with a nucleic acid sequence; and given the breadth of the claims which are drawn to any plants of any species containing a sequence that encodes polypeptides having at least 80% identity to SEQ ID NO: 2 or to a method of transforming a plant with the same; it would require undue experimentation by one skilled in the art to make and use the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldmann et al (Mol Gen Genet 208:1-9, 1987).

The claims are drawn to a transgenic plant containing a nucleic acid sequence that encodes a polypeptide having at least 80% identity to SEQ ID NO: 2, which is a fatty acid elongase from Arabidopsis.

Feldmann et al teach a transgenic Arabidopsis, wherein the fatty acid elongase gene having at least 80% identity to SEQ ID NO: 2 would be inherent therein and would have tissue specific expression.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
February 21, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600